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2	UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS
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4	TN DE NEW ENGLAND GOMBOUNDING N. MDI NO. 12 00410 DIJE
5	IN RE: NEW ENGLAND COMPOUNDING ) MDL NO. 13-02419-RWZ PHARMACY CASES LITIGATION )
6	) )
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10	BEFORE: THE HONORABLE RYA W. ZOBEL
11	BEFORE: THE HONORABLE RIA W. ZOBEL
12	
13	HEARING ON MOTION TO DISMISS
14	HEARING ON MOTION TO DISMISS
15	John Joseph Moakley United States Courthouse
16	Courtroom No. 12 One Courthouse Way
17	Boston, MA 02210
18	June 18, 2014
19	3:00 p.m.
20	
21	Catherine A. Handel, RPR-CM, CRR Official Court Reporter
22	John Joseph Moakley United States Courthouse One Courthouse Way, Room 5205
23	Boston, MA 02210 E-mail: hhcatherine2@yahoo.com
24	L marr. moadhermezeyanoo.com
25	

## 1 APPEARANCES: 2 For The Plaintiffs: Hagens, Berman, Sobol, Shapiro LLP, by JESSICA ROSE 3 MacAULEY, ESQ., 55 Cambridge Parkway, Suite 301, Cambridge, MA 4 02142; 5 Lieff Cabraser Heimann & Bernstein, LLP, by MARK P. CHALOS, ESQ., One Nashville Place, 150 Fourth Avenue, North, Suite 1650, 6 Nashville, TN 37219-2423; 7 Branstetter, Stranch & Jennings, PLLC, by J. GERARD STRANCH, IV, ESQ., and BEN GASTEL, ESQ., ESQ., 227 Second Avenue North, 8 Nashville, TN 37201-1631; 9 Cohen, Placitella & Roth, P.C., by MICHAEL COREN, ESQ., 2 Commerce Square, 2001 Market Street, Suite 2900, Philadelphia, 10 PA 19103; 11 Feldman Wholgelernter Tanner Dodig & Weinstock LLP, by THOMAS B. MARTIN, ESQ., 21st Floor, 1845 Walnut Street, 12 Philadelphia, PA 19103; 13 Leader, Bulso & Nolan, P.C., by GEORGE NOLAN, ESQ., 414 Union Street, Nashville, TN 37219; 14 Kinnard Clayton & Beveridge, by DANIEL L. CLAYTON, ESQ., 15 The Woodlawn, 127 Woodmont Bloulevard, Nashville, TN 37205; 16 For the Defendants: 17 Alexander Dubose Jefferson & Townsend LLP, by MARCY HOGAN 18 GREER, ESQ., 515 Congress Avenue, Suite 2350, Austin, TX 78701-3562; 19 Nutter, McClennen & Fish LLP, by SARAH P. KELLY, ESQ., 20 World Trade Center West, 155 Seaport Boulevard, Boston, MA 02210-2604; 21 Fulbright & Jaworski, LLP, by YVONNE K. PUIG, ESO., 98 San 22 Jacinto Blvd, Suite 1100, Austin, TX 78701; 23 Blumberg & Wolk LLC, by JAY J. BLUMBERG, ESQ., 158 Delaware Street, Woodbury, NJ 08096; 24 Gideon, Cooper & Essary, PLLC, by C.J. GIDEON, JR., ESQ., 25 and CHRIS J. TARDIO, ESQ., 315 Deaderick Street, Suite 1100, Nashville, TN 37238.

## 1 PROCEEDINGS (The following proceedings were held in open court before 2 3 the Honorable Rya W. Zobel, United States District Court Judge, United States District Court, District of Massachusetts, at the 4 5 John J. Moakley United States Courthouse, One Courthouse Way, 6 Boston, Massachusetts, on June 18, 2014.) 7 THE COURT: Good afternoon. Please be seated. 8 COURTROOM DEPUTY CLERK URSO: This is In re: New 9 England Compounding, MD-13-2419. 10 THE COURT: For the plaintiffs, who is here? 11 MS. MacAULEY: Jessica MacAuley. 12 THE COURT: Ms. MacAuley? 13 MS. MacAULEY: Yes. Hagens, Berman, Sobol, Shapiro, 14 lead counsel. 15 MR. CHALOS: Good morning, your Honor -- good 16 afternoon, your Honor. Mark Chalos for the plaintiffs' 17 steering committee. 18 MR. STRANCH: Good afternoon, your Honor. Gerard 19 Stranch on behalf of the plaintiffs' steering committee. 20 MR. CLAYTON: Good afternoon. Daniel Clayton with 21 the plaintiffs' steering committee. 22 THE COURT: Okay. 23 MR. NOLAN: Your Honor, I'm George Nolan from 24 Nashville also here for the PSC. 25 THE COURT: I'm sorry. You're for whom?

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               MR. NOLAN: With the plaintiffs' steering committee.
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               THE COURT: Oh, plaintiffs.
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               MR. GASTEL: Good afternoon, Judge. Ben Gastel, also
      here for plaintiffs' steering committee.
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               MR. COREN: Good afternoon, your Honor. Michael
      Coren, co-chair of official creditor's committee, but today
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 7
      I'll be here wearing my plaintiffs' hat on the Premier motions
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      in front of you.
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               THE COURT: Premier is the New Jersey?
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               MR. COREN: Yes, your Honor.
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              MR. MARTIN: Your Honor, Thomas Martin, also here for
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      the plaintiffs' motion, on the Premier motion.
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               THE COURT: Now we go over to this side.
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               MS. GREER: Your Honor, Marcy Greer for the Saint
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      Thomas entities and the Ascension parties.
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               THE COURT: Greer for Saint Thomas?
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              MS. GREER: Yes, your Honor, and the Ascension
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     parties.
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               MS. PUIG: Same, your Honor. Yvonne Puig, lead
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      counsel for the Saint Thomas entities and the Ascension
      entities.
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22
               THE COURT: I'm sorry. Your last name is?
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              MS. PUIG: Yvonne Puig, P-u-i-g, your Honor.
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               THE COURT: Thank you.
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               MS. PUIG: Thank you.
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               MS. KELLY: Your Honor, Sarah Kelly for the Saint
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      Thomas entities and the Ascension parties.
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               MR. GIDEON: Your Honor, C.J. Gideon on behalf of
      Saint Thomas Outpatient Neurosurgical Center, Howell Allen
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      Clinic, John Culclasure, Debra Schamberg, Specialty Surgery
      Center, Ken Lister, M.D., and Kenneth Lister, M.D., PC, along
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 7
      with Chris Tardio from my office.
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               MR. TARDIO: Good afternoon, your Honor.
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               THE COURT: Your last name?
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               MR. TARDIO: Tardio, T-a-r-d-i-o.
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               MR. BLUMBERG: And I'm Jay Blumberg from the firm of
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      Blumberg & Wolk on behalf of the Premier defendants in New
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      Jersey.
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               THE COURT: That's it?
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               Now, is everybody who announced his or her name going
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      to argue?
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               MR. STRANCH: I don't believe so, your Honor.
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      think you just got to meet everybody today.
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               THE COURT: I'm happy to meet everybody.
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               Could I have a show of hands as to who is going to
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      argue? You're kidding?
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               MR. STRANCH: It's only half of us.
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               THE COURT: Well, let me first apologize for this
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      constantly-changing time. What happened was that a defendant
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      decided not to plead and go to trial instead. So, we finished
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1 the criminal trial this morning and the jury is out, which may 2 be yet another interruption since they should have had a 3 verdict long ago, and we also have a couple of other criminal cases that are waiting in the wings. 4 5 So, I do not think that I could even give 15 minutes to each of you and I hope that you will make some arrangements 6 7 so that we can finish within an hour or so all of your 8 arguments. If you need to talk to each other, do that and 9 tell me how long each of you is going to be or we'll simply 10 start. To the extent -- yes. 11 MR. STRANCH: From the PSC's perspective, we've 12 already divided that up, your Honor, and that's fine with us. 13 THE COURT: So, how much are all of you going to take 14 together? 15 MR. STRANCH: I think we can do it in half an hour or 16 less, all of us. 17 THE COURT: I mean, I assume that the plaintiffs' 18 arguments are substantially identical, no matter who the 19 defendant is. That is, there are no more separate plaintiffs 20 who have different arguments from --21 MR. STRANCH: That's correct, your Honor. 22 THE COURT: Okay. Now, with respect to the 23 defendants, I think that the major ones are Saint Thomas and 24 Ascension. Premier is sort of a little less, I think. 25 MR. BLUMBERG: I don't know what you mean by "a

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      little less," but there are different issues.
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                           There are different issues.
               THE COURT:
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               (Discussion off the record.)
               THE COURT: So, I think we'll start with the Saint
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      Thomas defendants. So, how much time will you take
      collectively?
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               MS. GREER: The Saint Thomas entities and the
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      Ascension parties will take -- together with the Tennessee
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      clinic defendants will take -- 25 minutes?
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               MR. GIDEON: Yes.
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               MS. GREER: 25 minutes, and Premier will take five.
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               THE COURT:
                          Okay. So, who will start?
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               MS. GREER: Your Honor, I'll be prepared to start for
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      the Saint Thomas entities and the Ascension parties.
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               THE COURT: Right. I think it is appropriate for
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      counsel who argue to do so seated because the microphone
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      doesn't reach high enough and the people who are on the phone
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      elsewhere can't hear you unless you speak directly into the
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      microphone. Okay?
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               MS. GREER: That's fine.
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               THE COURT: So, at least you can be comfortable.
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               MS. GREER:
                          Thank you, your Honor.
23
               THE COURT: All right. Ms. Greer, you may begin.
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               MS. GREER: Your Honor, if I may, I'd like to start
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      with the Saint Thomas entities' motion. The Ascension
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parties' motion keys off of that and provides additional grounds for the motion to dismiss.

I have handed up to the Court a schematic drawing of an organizational chart that I think will be helpful to guide -- yes, your Honor -- to guide our discussion. I've provided it to the other parties as well. It just simply reflects the corporate structure that is in play here.

We have some additional arguments as to why Tennessee law would not impose liability upon the Tennessee clinic defendants, which is the basis for our vicarious liability.

THE COURT: This is the healthcare law?

MS. GREER: The healthcare law and the -- exactly. And our co-defendants are going to address that. So, rather than duplicate that presentation, I'm going to focus just on the allegations that defeat vicarious liability.

So, looking at this chart, just to understand schematically, because it helps me visually, what the plaintiffs are trying to accomplish and must accomplish here in order to have a claim for vicarious liability against any of the parties that I represent. They have to break through this dotted red line (indicating), which is based solely on a 50 percent ownership of the STOPNC clinic by Saint Thomas Network.

THE COURT: Is that because the two entities on the right side of the paper are the only operating ones, if you

will? That is the ones who had something to do with the injections.

MS. GREER: That's correct, your Honor. STOPNC was the entity that administered the injections. None of my clients injected MPA. None of them ordered it or bought it from NECC. Howell Allen is the other 50 percent owner of STOPNC and that's why they have a 50 percent dotted line as well.

THE COURT: So, they also had nothing to do with injecting anybody?

MS. GREER: I'll let them address that. They are involved with the clinic on more of a day-to-day basis.

Their employees, Dr. Culclasure and Nurse Schamberg, were also directors, medical and health directors of the clinic. So -- but none of our employees cross over to this entity right here (indicating).

And I think there are a couple of things that are really important to understand from the outset, and I'm sure the Court read our papers and understands our position, but one is that Saint Thomas Network is not a 100 percent owner. It is a 50 percent owner, which means, by definition, it does not have legal control over this entity. Very different from a lot of the alter ego cases that I'm sure the Court has seen where you've got a principal that either owns or completely dominates the other entities such that piercing the corporate

veil would be appropriate.

Another feature of this particular scenario --

3 THE COURT: Excuse me.

Are these companies on the left operating companies of one kind or another or are they simply -- is it simply a holding company?

MS. GREER: Well, at the top of the chain is a holding company in it, but then there are operating companies as well. So -- but they are all nonprofit entities and that's another unusual feature of this.

Usually when you're piercing the corporate veil, it's for-profit entities or individuals who are taking money out of the company where the veil is sought to be pierced, and here we've got a Tennessee for-profit LLC, STOPNC, and they're trying to pierce the veil up to each one of these entities on this side of the equation, and to go through each chain they have to produce evidence and to start they have to have specific allegations, allegations that would suffice under Tennessee law, and Tennessee law is very strong on alter ego. It respects corporate separateness. When companies are separately incorporated and separately run, you have to show quite a bit to get past their separate corporate veils.

And we've cited to the Court the law. It's not different from a lot of states, but it is very strong and there is a presumption against it, and to start again, they

have to allege certain things.

THE COURT: What does the not-for-profit part add to this?

MS. GREER: Well, I can't state a principle of law that supports not for finding alter ego against a nonprofit. Certainly it can be done, but I will submit to you that just on the number of cases I've read throughout the country, it's very rare because the objectives are different. We've got companies that are non-profits based in faith-based ministries. That is what they do. They are not trying to make a profit or pull money out of STOPNC or anything else. It's an investment that they have had and based on that, the plaintiffs are trying to push all of the liability up to these five entities (indicating).

And our -- the reason we're here today is to test the viability of those allegations, because there are cases, like the *Edmonds* case that we cited, that say the kinds of allegations that they're making are not enough to support a verdict under Tennessee law.

So, to take that a step back to where we are at the pleading stage, if those allegations if proved would not support a verdict against my clients, then they should be dismissed at this stage because this is a very, very expensive proposition for our clients to be in an MDL and to have discovery. It's a very complicated and drawn-out process and

our position is we shouldn't be here. We didn't have anything to do with these injections. We didn't have anything to do with procuring the MPA from NECC, and we're only in it on these vicarious liability claims and agencies. So, we want to really have the Court take a deep look at this because the kinds of things that they're alleging -- again, I'm going to focus on the Saint Thomas entities first -- are things like a common name.

Well, Saint Thomas is a pretty famous name. I thought at one point about looking up how many entities in the United States are called Saint Thomas that are based in healthcare and I stopped because it was going to take too much time, but it is a very common name.

The fact that there is some common ownership is not enough. That has never been sufficient to pierce the veil. It is an extraordinary remedy, to be used sparingly when the corporate form has been misused, and that's what I will submit to you, your Honor, is conspicuously absent from these pleadings, is allegations that would support that we misused the corporate form, that we did not respect STOPNC's separateness.

The things that they said in that regard are things like, Well, you provided some financial services and management services. That's not enough to pierce the veil.

If that's not done on an arm's-length basis, which it was

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here, that's not enough. We didn't share employees. said, Well, you have the right to appoint two directors to the board of directors. As we cited the Supreme Court of the United States, that's not enough to shift liability. They mention that --THE COURT: Well, I don't look at these things 7 individually, do I? As I understand it, the plaintiffs are supposing a collection of facts. MS. GREER: Absolutely, that's correct. 10 THE COURT: Name, plus other things. MS. GREER: The totality of the circumstances. 12 THE COURT: Right. 13 MS. GREER: Exactly, but what I'm suggesting to you -- and I'm looking at each one and then I want to explain to 15 you that collectively, for example, in the Edmonds case, they 16 found that the principal was so completely dominating the 17 subsidiary, had complete control and dominion or domination --18 they use different words -- that it would otherwise support 19 piercing the veil, and the court said, no, we're not going to pierce the veil because there's been no misuse of the corporate form here, and that's what's lacking here. 22 I mean, the Court, no doubt, has seen alter ego 23 allegations over the years, and the three features that are kind of -- what I call the real indicia that kind of cross all 25 lines are things like commingling of property and assets

and/or capitalization and diversion of corporate assets, and none of that is present in this case. All they've got is a 50 percent ownership, which, again, is not control. The fact that they provided a board room for STOPNC to have its board meetings -- you know, my church provides a place for our neighborhood association to have meetings as an accommodation because they're in the same community. That's not the kind of thing that warrants piercing the veil. What warrants piercing the veil is when you're really misusing the separate forms and those allegations are lacking here.

As to the Ascension parties, it's even more remote. They say absolutely nothing about Ascension. The only specific thing that they have said about either Ascension parties that would warrant piercing the veil even between these entities (indicating), not even getting all the way to STOPNC, is that we listed in our Form 990, which is a form we file with the IRS, that some of these entities were direct-controlled entities.

Well, there's a definition for that under the tax code, and that means if you own 50 percent or more, and because these are wholly-owned subsidiaries, of course, we had to list them. So, the allegations based on that have never been used. I've never found a case that a Form 990 representation was used to pierce the veil. So, at a minimum, those entities should be dismissed.

And then another issue that we raise as a matter of law is the prohibition against the practice -- corporate practice of medicine in Tennessee. Tennessee, like many states, has a law that says we do not want corporations directing and controlling the professional judgment of physicians.

Here, most of the allegations, agency and otherwise, are based on the actions of John Culclasure, who is a physician, who, again, was an employee of Howell Allen, a medical director of the clinic STOPNC, and to the extent that the veil could be pierced or even agency allegations could be made based on his actions, that is barred as a matter of law under Tennessee law. We made that argument in our motion. It was not responded to.

And I know I'm running low on time, so let me make a brief statement on the agency issues because those are different.

As to the agencies, again, the focus is on the actions of two individuals who there's been no showing that they had actual authority of any kind to act on behalf of my clients. They did not have apparent authority. There's not been an allegation that someone was dealing with Nurse Schamberg and thought they were dealing with any of my clients, and there's been no ostensible agency.

The only cases that they've cited have been cases

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      that involved emergency-room practitioners and that is a very
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      different model. If you walk into an emergency room, most
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      people who are not familiar with healthcare will assume that
      the people that work there are employees of the hospital.
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      that's why Tennessee and other states have laws that require
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      you to have some sort of disclaimer if you don't want to incur
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      the liability.
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               This is very different. The STOPNC clinic is a
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      different building. It has a different entrance, different
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      signage. It's completely separate from our facility, the
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      Saint Thomas facilities. And so, to suggest that we would
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      have to disclaim another building and say that's not ours
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      makes no sense, and they don't cite any law for that
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      proposition. So, we would ask that the Court dismiss the
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      Ascension parties and the Saint Thomas entities on the
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      pleadings.
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               THE COURT:
                          The Saint Thomas entities are on the left
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      side of your paper?
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               MS. GREER: Yes, your Honor.
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               THE COURT: You don't speak for the STOPNC?
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               MS. GREER: No, your Honor.
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               THE COURT:
                           Okay. Thank you.
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               Who else wants to speak for Tennessee?
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               MR. GIDEON: C.J. Gideon and Chris Tardio wish to
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      divide the remaining time.
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MR. TARDIO: Good afternoon, your Honor. Chris Tardio.

As your Honor picked up on, we represent the entities on the right-hand side of this chart, and I want to take a few minutes to talk about the Healthcare Liability Act, which your Honor mentioned a moment ago at the beginning of Ms. Greer's presentation, and then I'll turn the presentation over to Mr. Gideon to deal with the bulk of the global issues.

We have two motions pending, one deals with pre-suit notice and certificate requirements, another deals with the global motions -- or the global issues of law. I'll address briefly the Healthcare Liability Act and then the statutory requirements.

In Tennessee in 2008, the legislature passed the first round of tort reform and the first round of pre-suit requirements in at that time medical malpractice actions. That's what they were called. And the statute was amended over the years and what we have now is two separate statutes, 121, which requires pre-suit notice of a healthcare liability action at least 60 days before suit is filed.

THE COURT: How does the statute define a healthcare liability action?

MR. TARDIO: That's the heart of the issue here. A healthcare liability action in Tennessee is defined as any claim for injury -- any claim against a healthcare provider

1 for injury related to the provision of healthcare services. If you look at the legislative history behind that 2 3 statute -- that's 29-26-101, the definition. If you look at the legislative history -- I mean, obviously, it's very, very 4 5 broad to some --6 THE COURT: I assume it does not apply to 7 pharmacists. 8 MR. TARDIO: It does apply to pharmacists. THE COURT: Pharmacists who sell a drug are deemed to 9 10 be providing healthcare services? 11 MR. TARDIO: If the claim is for injury related to 12 the provision of healthcare services, then, yes, the claim 13 falls under the Healthcare Liability Act and the -- another 14 important part of the act is that the language says 15 "regardless of any other claims or theories in the complaint." 16 So, if there is a claim in that complaint for 17 injury -- claim against healthcare provider for injury related 18 to the provision of healthcare services, the requirements of 19 the act apply, 121 the pre-suit notice requirements and 122 20 the certificate requirements. And the -- if you look at the legislative history 21 22 behind the act -- and we've cited some of it in the 23 briefing -- the intent was to avoid exactly what happened 24 here, plaintiffs attempting to plead around the requirements 25 of the act. The sponsoring legislator said in some of the

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legislative history that we have cited, "It is advantageous in the minds of some plaintiffs to keep their lawsuit out from under the healthcare provider statutes, make a cause of action look like something it isn't at its core." So, you spend most of your time at the outset trying to define what the cause of action is. We're hopeful that this statute will obviate some of that and reduce some of the time spent. These claims are for injury related to the provision of healthcare services. THE COURT: So, if somebody sells prosthetic devices, for example, that would also be a healthcare-related injury? MR. TARDIO: If it's against the healthcare -- if the claim is against the healthcare provider and the injury --THE COURT: But that begs the question, you know, whether somebody who sells a product is a healthcare provider. That's a distinction that the plaintiffs certainly make. MR. TARDIO: I don't know that the plaintiffs make any argument that we're not healthcare providers. THE COURT: Well, they make the argument that the statute applies to those who provide the service, not to those who sell a product, as I understand it. MR. TARDIO: Well, they've chosen -- what the plaintiffs have done is said, We're not suing you. We're bringing a product liability claim. We're not suing you as

healthcare providers, but the statute -- that's not the way

the statute is written.

The statute is written broadly, such that if the injury claimed is related to -- not arising from, related to healthcare services, it falls within the act, regardless of any other claim in the complaint, and that's -- no matter how you twist --

THE COURT: Healthcare services? Related to healthcare services?

MR. TARDIO: Yes, ma'am, and that's defined -healthcare provider and healthcare services are both defined
within the act, and if you look at allegations in these
complaints, that's what the claims are for. They're for -regardless of any other claims in the complaint, 121 and 122
must be followed.

Let me just very briefly touch on the 122, which is the certificate requirement deficiency.

If the Healthcare Liability Act applies, and it does under the broad definition, at least that's our position, you have to file a certificate of good faith or certificate of merit with the complaint.

43 cases didn't have one filed with it. About a dozen are easy. They specifically alleged negligence against healthcare provider and injury related to the provision of healthcare services. There's no excuse for not filing one in those cases. Those cases should be dismissed with prejudice

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      under the plain language of the statute.
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               THE COURT: Is it clear that the statute does not
 3
      permit an amendment of the complaint?
               MR. TARDIO: The Vaughn case, which we've cited, and
 4
      our Supreme Court denied cert and it said that an amendment is
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      not sufficient under the act to cure deficiencies. You can't
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      amend later. And if you think about the policy reasons behind
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      it, the intent of the certificate requirement is that when you
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      filed the complaint, you've had somebody -- an expert look at
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      the case and certified its merits. If you filed that three or
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      four months later, it defeats the intent behind the act.
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               THE COURT: Excuse me one moment.
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               (Discussion off the record at the bench.)
14
               THE COURT: Excuse me one moment.
15
               Are counsel in the criminal case here?
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               COURTROOM DEPUTY CLERK URSO: John is here.
                                                            Mr.
17
      Butters is -- he's up in the library.
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               (Discussion off the record at the bench.)
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               THE COURT: I'm sorry. Go on.
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               MR. GIDEON: Your Honor, I'm going to finalize our
      presentation on behalf of the Tennessee clinic defendants.
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               You need to add on the right side of the page some
      additional names. We also represent John Culclasure, who is
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      an M.D., anesthesiologist who administered a number of
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      injections. Debra Schamberg, who is a Registered Nurse who
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was the practice operator for STOPNC, Registered Nurse. She is named as an individual defendant.

THE COURT: As to them, you're invoking the statute that says they have to certify ahead of time?

MR. GIDEON: Yes, ma'am.

As well as Howell Allen, which is a professional corporation made up of a group of neurosurgeons.

To track what Mr. Tardio said just a moment ago, there's some additional reasons why the Products Liability Act of Tennessee does not apply by definition. First, what was delivered here, even as it is described in the master complaint, is services. These patients predominantly had lower back pain, serious lower back pain. They were referred to STOPNC for the epidural steroid injections, and a physician administered the injection in the epidural space. Granted, the physician used methylprednisolone acetate secured from NECC, but there wasn't a sale of MPA to any of the patients.

THE COURT: How did the physicians treat this service and -- with an injection on their bills?

MR. GIDEON: The Howell Allen Clinic billed for the physician fee by Dr. John Culclasure, and if the Court will look at Exhibit 8 to the Reed complaint, there is also a charge for a facility fee that is approximately \$1,042. There is no bill for MPA. There is no bill of sale for MPA. There is no discrete individual charge for the steroid. So, we

respectfully submit to the Court there was no sale.

And one of the reasons why the Tennessee Products

Liability Act does not apply, your Honor, is because (A) there
was no sale, but for the act to apply, there has to be a sale
by a seller who is engaged in the sale of those products. So,
it eliminates this by definition.

Secondly, there is no tangible product or good here. There is a service, the delivery of a healthcare service, which I know this Court is familiar with. The vast majority of the jurisdictions that have looked at this issue, even when there is a defective product involved like the defective devices in the mouth and the back that we cited in our case submissions, always treated predominantly as a service and that has been the rule in Tennessee as well.

Tennessee is one of those states that does not distinguish between a sale versus a service in the same transaction. The Court looks to see what is the predominant aspect of the relationship, which in this case is a service, and if it is, the products act does not apply.

Finally, Mr. Tardio didn't touch on this fact, but there is a definition of healthcare providers that fall within the act. It extends to hospitals, ambulatory service centers, physicians, even certified nursing assistants in nursing homes, to give you some idea of the intended breadth of the act.

So, one of the principal points for the Court to

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address is, the plaintiffs wish to impose liability without fault on these healthcare providers. The Healthcare Liability Act of Tennessee says there cannot be liability without fault. If we are responsible, we are responsible only if they prove there was a departure from accepted standards of professional practice that caused an injury which would not have otherwise occurred. THE COURT: But we can't deal with that at the moment because we do not have evidence yet and there's been no discovery on this issue at this point, right? MR. GIDEON: I'm not asking for summary judgment on the merits. THE COURT: I understand. MR. GIDEON: I'm saying that the substantive law that should apply is the Healthcare Liability Act, not the Products Liability Act. Two additional points that I think the Court should focus on. We filed our motion to dismiss on January 10th, 2014. We raised nine grounds, eight of them are due to be granted and should be allowed based on the plaintiffs' March 28th, 2014 response. The product liability claims against Drs. Culclasure, Lister, and Schamberg should be granted. They aren't sellers under any scenario, any argument at all. The product

liability claim against Howell Allen should be granted.

didn't sell anything and they admit that in their response.

The claims of ordinary negligence should be dismissed. The

Tennessee Consumer Protection Act claim should be dismissed.

It's clear that that does not apply here. The medical battery claims were not contested, and the failure to warn or lack of informed consent claims should be dismissed as well.

The only thing that should remain as to our healthcare provider clients is a claim under the Healthcare Liability Act, nothing more.

We also respectfully submit that civil conspiracy and agency should be dismissed. Why should the civil conspiracy claim be dismissed? When your Honor looks at the materials, you will see, taken in the light most favorable to the PSC — they say that Debbie Schamberg was told by a representative of NECC that she had to provide a patient list to get a further supply of MPA. She said I can't predict who will be here next week. And they said any list will be fine. So, she gave them the list, and even their allegations establish she was doing so with the intent to comply with what she was told was Massachusetts law.

That's not a civil conspiracy. There is no intent to violate the law by Debbie Schamberg and, in addition, in Tennessee a compounder can provide product in anticipation of a prescription. An individual prescription is not required as a matter of law.

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Vicarious liability and agency. There is absolutely nothing in these papers that would establish that my clients should be held responsible for NECC. There's not even a showing that we controlled their methods, means or manner, which in Tennessee is required in order to establish agency. And, last, as to this claim of special relationship, the Limbough case and Turner vs. Jordon case, in both of those cases the plaintiff was able to show that the defendant had actual knowledge, actual knowledge of the threat of harm created by a third party. In this case there is no such proof at all. Any additional questions, your Honor? THE COURT: Thank you very much. MR. GIDEON: Thank you. THE COURT: Let me interrupt again for a moment. May I see Mr. Wortmann and Mr. Butters, please? (Discussion off the record at the bench.) THE COURT: I'm sorry. This jury is giving me trouble. We'll have to interrupt once more in order to deal with the jury, but, in the meantime, we will continue with this case. MR. STRANCH: Your Honor, we have a notebook that we put together as part of the plaintiffs' responses. It has some documents, statutory sections and other things that we're

going to be referring to. We've provided copies for the

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      defendants, and we'll hand this up to you if that's okay.
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               THE COURT:
                          Do you have two copies, by any chance?
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               MR. NOLAN: Yes, we do.
               THE COURT: So, maybe we can give one to the law
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      clerks, if you would, please.
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               MR. STRANCH: Sure.
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        (Attorney Stranch hands binders to the Court and law clerks.)
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               MR. NOLAN: Your Honor, does the Court wish to
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      address the argument regarding STOPNC and their application to
      the Products Liability Act first or the --
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               THE COURT: Whatever you wish to do.
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               MR. NOLAN:
                          Sure.
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               THE COURT: But within the time limits, please. So,
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      how long are you going to be?
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               MR. NOLAN: Your Honor, I will be no more than 30
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      minutes.
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               I'm George Nolan from Nashville and I will be
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      discussing the application of the Tennessee Products Liability
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      Act to these sellers, and I think it's important for the Court
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      to understand how the Tennessee Products Liability Act of 1978
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      works.
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               That statute provides, your Honor, that all
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      businesses that sell or distribute products in Tennessee are
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      required to stand behind those products and cover any harm
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      caused by those products under certain limited circumstances.
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THE COURT: This is not limited to medical products? No. The act, your Honor, defines the MR. NOLAN: term "seller" very broadly. It makes no effort to exclude healthcare providers from the definition and, in fact, if you turn in your notebook, your Honor, to the first tab, you will see how the statute defines the term "seller" and it's very broad and it includes some words that the defendants don't focus on in their arguments. It, "includes a retailer, wholesaler or distributor, and means any individual or entity engaged in the business of selling a product, whether such sale is for resale, or for use or consumption." It's a very broad definition, no effort to exclude healthcare providers. Your Honor, we know from the defendants' deeds and words that they fit that definition. Ιf you turn in your booklet to Tab No. 20. --THE COURT: Well, booklet this is not. It's a major book. MR. NOLAN: The exhibit notebook might be a more apt way of putting it. Tab No. 20, your Honor, is a letter sent by the defendants Saint Thomas Outpatient Neurosurgical Center less than two weeks after this outbreak became public knowledge and, as you can see here, the clinic writes to NECC and, first of all, accuses that company of breaching the warranty of merchantability, and then says: "Specifically, the below

listed goods have been recalled and/or no longer fit for use/sale due to contamination or suspected contamination."

So, less than two weeks after this happened, this clinic is writing to NECC and threatening to sue NECC because the products are not good for use or resale.

So, clearly, your Honor, they fit within the broad definition of "seller" that we find under the products liability statute. And in Tennessee, your Honor, anyone who is a seller is required to stand behind that product under certain limited circumstances, and the circumstance implicated in this case is when the manufacturer is determined to be insolvent. That's the baseline rule.

That is the public policy decision that our legislature made, and it's a very important public policy because our legislature decided that when something like this happens and these terrible losses occur, the loss doesn't rest within the innocent victims. It rests with the businesses who make the business decision to import products into Tennessee made by a manufacturer that doesn't have the wherewithal to stand behind those products, and they're asking this Court to make a huge and very detrimental change to Tennessee products liability law that's been the law of Tennessee for the last 36 years, your Honor.

And I think it's important for the Court to also focus on the definition of the term "seller" in the Healthcare

Liability Act, and if you look at Tab 3 of our notebook, your Honor, you find how that particular term is defined in the healthcare liability statute and, as you can see, your Honor, the scope of that statute is key to healthcare services. It doesn't say anything about products. "Healthcare services" is a defined term, and our legislature wrote a very thorough definition that includes any manner of services, but it never anywhere says that services means products. In fact, the words good, goods, service — product or products, never appear anywhere in the statute.

So, the defendants are asking this Court to judicially insert words into the Healthcare Liability Act which are not present in that statute.

It would have been so easy for the legislature to say healthcare services includes all care, products, goods and services provided to the patient, but that's not what our legislature did, your Honor.

So, the defendants are asking this Court really to go out on a limb. They're asking this Court to reverse 36 years of products liability law and they're asking this Court to rule that our legislature decided to completely change Tennessee's scheme for allocating loss caused by harmful products without ever expressly saying so.

And, your Honor, a ruling like that, not only would it be unjust, your Honor, it would be -- it can cause this

litigation to boggle on for years, and here's why:

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If the Court finds that the plaintiffs are allowed to prosecute product liabilities claims against these defendants as sellers, then these defendants are required to stand behind the product and they are jointly or severally liable for the harm caused by the product. Suddenly the case becomes simple and it will move to resolution under very just circumstances and in accordance with public policy adopted by the Tennessee legislature, but if the Court adopts the defendants' position, then we'll be here a decade from now arguing over the defendants' compared default defenses, and the fact that they want to try these cases to the jury verdict form that has a long list of parties, including the FDA and the CDC and the Massachusetts Board of Pharmacy and the Tennessee Board of Pharmacy, and they want to attribute fault to all of those particular players and that, your Honor, that would be completely contrary to how our products liability system is set up.

Your Honor, in our statute we have a provision that's not present in any other state and that's a provision that says that there is one circumstance and only one circumstance in which healthcare providers are not considered sellers and that's when the product is a silicone gel breast implant and that statute was passed in '93, your Honor, at the request of a very highly-regarded woman senator in Tennessee who was a

breast cancer survivor and it was in the midst of the Dow

Corning litigation in which -- at a time when thousands and

thousands of cases across the country were pending against Dow

Corning and this particular senator thought that it was unfair

that some of the women in Tennessee were having their claims

time barred by Tennessee's ten-year statute of repose in

products cases. So, she proposed a bill to extend the statute

of repose from ten years to 25 years for that particular

product, and when she proposed that bill, the medical

community pushed back and they lobbied into the bill, your

Honor, a statutory carve-out indicating that for purposes of

that product only, that product only, that healthcare

providers are not considered sellers and that carve-out, your

Honor, is found in your booklet under Tab 2A.

So, the statute is very clear. There's only one circumstance in which healthcare providers are not considered sellers and that's when we're discussing a silicone gel breast implant, and in all other circumstances, in all other circumstances, your Honor, the healthcare providers have the same obligations as any other business that sells a product.

And, your Honor, as the Court observed, we do specifically allege in our complaint that these clinics sold this stuff. They broke out the charges separately. They charged separately for the doctor's service and they sent a bill to Medicare and the other insurers for the injection

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      itself and the injection is the steroid. That's the only
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      reason for that transaction.
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               That concludes my portion of the --
               THE COURT: Thank you.
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               MR. NOLAN: Unless the Court has a question.
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               THE COURT: No, I do not.
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               MR. NOLAN:
                          Thank you.
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               THE COURT: I'm not exactly sure how to do this.
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      is arguing next?
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               MR. CHALOS: I am, your Honor.
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               THE COURT: How long will you be?
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               MR. CHALOS: About ten minutes probably.
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               THE COURT: I think Ms. Urso has gone to get the
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      jury. If you could just --
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               COURTROOM DEPUTY CLERK URSO: I'm sorry.
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               THE COURT: Don't all leave. If I could have one
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      chair in each of the front tables, that's all I need, just one
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      chair. Oh, yeah, we need two.
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               COURTROOM DEPUTY CLERK URSO: You can leave your
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      stuff. This will not take very long.
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               THE COURT: Okay. Bring the jury down.
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               (Pause.)
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               THE COURT: Sorry about this. And we will continue
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      with New England Compounding. I thank you for your
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      indulgence, but I've managed to take care of two cases in the
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1 interim. Mr. Stranch, you were next. 2 MR. STRANCH: Mr. Chalos will be next. 3 THE COURT: Okay. Mr. Chalos. MR. CHALOS: Yes, your Honor. Mark Chalos on behalf 4 5 of the plaintiffs' steering committee. 6 I'm going to address the Saint Thomas entities' 7 arguments that they should be dismissed at the threshold based 8 on the allegations in our complaint. I'm going to leave aside for now the Ascension entities. Those are the ultimate 9 10 corporate parent companies. 11 THE COURT: So, you're addressing the vicarious 12 liability products? 13 MR. CHALOS: Your Honor, yes, as well as some direct 14 liability that brings me to my first point. 15 Counsel for the Saint Thomas entities represent to 16 the Court that all of the allegations against her clients are 17 vicarious, and that's not entirely the case. 18 If your Honor -- again, in the notebook that Mr. 19 Nolan handed up to you, Tab 36 is Wayne Reed on behalf of his 20 deceased wife, Diana Reed, their lawsuit against these 21 entities, and this is a complaint that I'm going to refer to 22 from time to time during my argument as setting forth the 23 allegations that are operative for purposes of our discussion 24 today, and if your Honor will turn to Page 51 in Tab 36 of our 25 notebook.

THE COURT: Okay.

MR. CHALOS: Count XII claims against Saint Thomas, and Saint Thomas is defined for purposes of this complaint and this section to include Saint Thomas Network and Saint Thomas Health. I want to pause here for one second.

Saint Thomas Network is a company that essentially is a holding company. It has no employees and we don't know its asset situation, but it's our understanding it has no assets. Your Honor correctly identified these companies as not essentially operating companies. These are shells and there are various movements around. At one point the corporate owner of Saint Thomas Outpatient Clinic was a company called Saint Thomas Health Services.

THE COURT: Saint Thomas?

MR. CHALOS: Health Services.

Apparently, Saint Thomas Network was at one time known as Saint Thomas Health Services, that now refer to Saint Thomas Health -- I'm sorry. The entity they now refer to as Saint Thomas Health at one time was Saint Thomas Health Services as well. At some point somehow ownership transferred. It's unclear to us at this point. We have not yet gotten any discovery that's meaningful from these entities. They've produced I think some total of 51 pages of documents, two documents totaling 51 pages. So, to some extent we're limited in the information we have. Appears to

1 be some shells moving around and some flimflam going on at a 2 billion-dollar hospital, but we don't yet have the information 3 to really nail it down. But that said, we're at the pleading stage and our 4 5 obligation at the pleading stage is to plead enough facts to 6 state a claim for relief that's plausible on its face. 7 "Plausible" means it will raise a reasonable expectation that 8 this discovery will reveal evidence of the necessary elements. 9 That comes from the Twombly case. 10 So, looking at Count X, these are direct negligent claims, direct --11 12 THE COURT: X or XII? 13 MR. CHALOS: I'm sorry. XII, you're right, your 14 Honor. 15 The allegations here are that Saint Thomas, which, 16 again, includes Saint Thomas Network and Saint Thomas Health 17 and Howell Allen Clinic, were negligent in the manner in which 18 they operated Saint Thomas Neurosurgical, the clinic. 19 THE COURT: But if, as you say, they were shell 20 corporations, what obligation would they have had over the way 21 the surgical clinic operated? 22 MR. CHALOS: Well, they have an operating agreement 23 that is also in this notebook at Tab 39, which outlined, among 24 other things, the powers of the various entities and the flow 25 of the money and, as your Honor will see, it's a fairly dense

document. The money moved around, and what our allegations are -- when I say "moved around," moved from the clinic up through the Saint Thomas chain. They may call themselves nonprofit entities, but there's a lot of money, hundreds of millions of dollars moving around over there.

Ascension is a \$15-billion-a-year company. So, whether they call it profits, meaning they pay federal income tax on it, or they call it something else is immaterial for purposes of our discussion. But, in any event, these are allegations that they directly committed their own negligence. At least those entities did.

We also have claims that the Saint Thomas entities — that the clinic operated as an agent of those entities, both an actual agent and an apparent agent. Those do not require, nor does the direct negligence claim require any piercing of any veil. Those are independent claims for the bad conduct of these entities. And, again, we're at the pleading stage at this point. We still need to prove our case. We need to properly surmount a summary judgment motion at some point and we'll need to prove it to the jury at trial, but for now we're focused solely on the obligations of the complaint.

The allegations of apparent agency and actual agency—
THE COURT: Excuse me.

You make allegations about their obligation to -- with respect to the supplies from NECC.

MR. CHALOS: Yes.

THE COURT: Is that something that they would have been obligated to do under this operating agreement?

MR. CHALOS: Well, your Honor, again, at this point we have no real discovery from these entities. We have made allegations based on the information available to us and it's our understanding based on the information that we have at this point that they had a role in that.

The apparent agency claim arises from a number of facts. Correctly identified, it's a constellation of facts and they are set forth in the complaint as well. And, again, using the Reed complaint as an exemplar, starting on Page 50, Count XI, that sets forth the apparent agency and actual agency claims against Saint Thomas Hospital, and on Page 53 there are a number of allegations that set forth the claims of apparent agency against Saint Thomas Health and Saint Thomas Network. And, again, we're focused on the complaint, but I'd like to point your Honor to a few things.

These are facts that I think put context around the allegations and I think they also directly refute some of the points that counsel for Saint Thomas made. If your Honor will turn to Page 20 -- Tab 22 of the binder.

THE COURT: Tab 22?

MR. CHALOS: Tab 22. This is a photograph of how Saint Thomas represents itself in the national community.

This is a photograph taken on a main street downtown Nashville and it represents itself as, "One name, one healing community, Saint Thomas."

If your Honor would turn to Tab 23 of the notebook, it's another photograph. This is taken at the national airport. Again, Saint Thomas representing themselves to the national community and to the world, "One name, one healing community."

If your Honor would turn to Tab 24, this is the sign that patients see as they approach from a main street the Saint Thomas Hospital campus, and it says right on top, "Saint Thomas," and then on the bottom of the sign, "Outpatient services." It directs you to the main building.

If your Honor would turn to Tab 25, you'll see a map. This is the Saint Thomas facility. The clinic was located on the ninth floor right where it says, "Medical Plaza East."

If your Honor would turn to Tab 26, this is what the patients saw when they walked in the ninth floor of Saint Thomas Hospital. They saw a sign that says, "Saint Thomas Outpatient Neurosurgical Center."

Counsel for Saint Thomas entities suggested they had no obligation to clear up any notion that people going to Saint Thomas Hospital, when they walk into Saint Thomas Hospital and go to the ninth floor of Saint Thomas Hospital and go to the clinic called Saint Thomas, that they have no

obligation somehow to clear up the notion that this is somehow not affiliated with Saint Thomas in any way.

Honor would turn to Tab 28. This is Dr. Culclasure's hospital I.D. This is the I.D. that he would have on the outside of his clothes when he saw patients and injected them, and if you look on the back of it, it says, "This card is official property of Saint Thomas Health Services and must be surrendered when requested by hospital authorities," further supporting the notion that this clinic is in the hospital if they're controlling access to the facility.

I want to point out just a couple of other points of what Saint Thomas said to the community. Tab 29 is the letter that the clinic, Saint Thomas Clinic, sent to patients to inform them that they may be in grave danger because of a product that was injected into them at the Saint Thomas Clinic. What it highlights, it says either call us or visit the Saint Thomas Hospital emergency room. Why they would be directing the patients to a stranger entity is puzzling. It's them.

Tab 30 is a medical record from Diane Reed, deceased, patient at Saint Thomas. This is the record from when she was admitted into the Saint Thomas Hospital. If you look at the top, it says, "Saint Thomas Hospital" next to "Saint Thomas Health Services." This is the physician on duty, Dr. Motyka,

and Dr. Motyka writes, "The patient recently underwent a steroid epidural injection here five days ago." "Here," meaning the clinic in their building.

So, your Honor, I point those out. Those are documents that we've been able to pull together over the last period of time, some well after the complaints were filed. These complaints were filed some time ago. These put a context around the notion that these are -- it is, "one name, one healing community." It's a group of entities that are interrelated. They're interconnected. They call themselves here...

And I want to point out just one more, Tab 38 of the binder. This is Scott Butler, who was the CFO of the clinic, and he said -- this is a quote in the newspaper. He said, "This is a bad event for us, and obviously it puts a scar on our doctors, our patients and our hospital." This is the CFO of Saint Thomas Clinic. "Our hospital."

So, your Honor, at this point what we've alleged is more than sufficient to withstand a 12(b)(6) challenge.

THE COURT: If you are -- I mean, assume that these allegations -- I mean, these allegations are here. How far up the chain would they go for liability purposes? I mean, would you be able to catch, based on these allegations, Ascension Health Reliance?

MR. CHALOS: Well, Mr. Stranch will address that

issue. The answer is yes.

I want to point out one more thing to your Honor and then I'll stop and Mr. Stranch can take over on the Ascension question.

Tab 33 of the book, this is a chart that we created and it is a representation of the interrelationships among the Saint Thomas entities, Health, the hospital, Saint Thomas

Network and Saint Thomas Clinic. It's sort of a counterweight to the chart that they presented. They presented it in a way, obviously, they think supports their case, and we presented it in a way we believe supports our case and also more represents reality, and that's Tab 33.

So, we think at the very least our allegations as pleaded currently are sufficient for 12(b)(6) purposes to at least allege a cause of action against all of the Saint Thomas entities. Mr. Stranch will address the Ascension entities.

THE COURT: Thank you.

MR. STRANCH: Thank you, your Honor.

On the Ascension entities, basically, if you take a look at our briefs, we think we've covered it well within the brief, but what you see is that these are entities, starting first with Saint Thomas, that are operating as if they're one community, one set of hospitals, one corporation, and it appears that the corporate leanings are being used either for tax purposes or, you know, as a shell game maybe, you know,

but Ascension, when you go look at their tax forms -- and we've had no discovery from Ascension. They say they're a direct controlling -- they directly control the Saint Thomas entities. They're under their direct control. That's what they say.

They say also that Saint Thomas Outpatient

Neurosurgical Center is a related organization that is taxable as a partnership. In other words, Ascension derives revenue from Saint Thomas Outpatient Neurosurgical because it is a related entity that is taxable as a partnership because it's an LLC that's chosen to be treated as a partnership as opposed to an S Corp or C Corp.

And, frankly, your Honor, these sorts of allegations of agency, of corporate veil piercing, of vicarious liability, these are generally dealt with after full discovery has been done. And so -- you know, because they're highly factual intensive. These are not the sorts of allegations where, you know, you don't have to delve into, as you put it earlier, all of the facts as they come together, but here you do.

And so, we think that the 12(b)(6), at least as it relates to all of the agency, vicarious liability and other claims, should be denied. We should be allowed to do the discovery that we've already -- some we've already found, flush those things out.

THE COURT: You speak on behalf of the two Ascension

1 defendants? 2 MR. STRANCH: Yes. 3 THE COURT: Not the Saint Thomas Health and Saint Thomas Network? 4 5 MR. STRANCH: Well, I think that motion should be denied as well, your Honor, but I'm speaking --6 7 THE COURT: You're now not addressing the 8 relationship they have may. 9 MR. STRANCH: I'm not. I'm just discussing 10 Ascension. 11 Ascension says we directly control the Saint Thomas 12 entities. You know, we think that is by itself enough to let 13 us get some discovery. When you add in, you know, the issues 14 as it relates to STOPNC also being listed as something that's 15 a related organization for them, we think we should be 16 entitled to do that discovery and, frankly, even if it's dismissed from the case, we're still going to get the 17 18 discovery and then maybe we'll just be amending to add it back 19 in later. So, we think it's better to move forward and 20 consider it on a summary judgment record, you know, at an 21 appropriate time. That's Ascension. The other issue that I'm talking about -- and I'm 22 23 trying to go quickly, your Honor, to be cognizant of the time 24 and I do think this has been briefed well. So, I'm trying not

to cover what's already been briefed for the Court.

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THE COURT: Yes, I appreciate all your briefs.

MR. STRANCH: Thank you. And I hope you've got a couple of good law clerks to help you carry it.

THE COURT: I mean the briefs of all the people, not just all of yours. All the people who are here.

MR. STRANCH: Well, your Honor, I'm also going to talk about the product liability actions because there was a group of approximately 40 cases that were filed initially only as product liability actions and were not originally a product liability action and a healthcare liability action, and that arises because of the way that Tennessee law works.

We're a one-year statute state. And so, some of these cases came in the door to the lawyers where they didn't have 60 days to serve a notice beforehand, and it's not -- and get the extra tolling of the statute that the extension of the statute of limitations that you get under 121 for serving an appropriate notice. And so, those lawyers are faced with the decision, Do I file my products case and know I've preserved that statute when I don't think it has anything to do with the healthcare liability action. Go ahead and serve my notice, but, alternatively, I am going to plead a Healthcare Liability Act claim on down the road and let that 60 days run and then amend to add those claims in.

You know, I can tell you, your Honor, as a plaintiff's lawyer, one thing you don't do is let a statute

expire without a case being on file. And so, those lawyers in that situation, and we should include some of my cases, they file the complaint as products. We filed ours. We made it clear, this is not Healthcare Liability Act. This is only for the sale of the MPA, and I can tell you the insurance records for some of my clients, the MPA is a specific line item that they're charged for. They get one insurance record that goes to the Howell Allen Clinic that's for the services provided. They get a separate one that's for the facilities. It's for the substance, the product itself and other materials that are used during the procedure, you know. So, they get two separate insurance bills.

And so, we break all that down and we filed that case first, you know. We said in there specifically we are going to assert a Healthcare Liability Act claim on down the road. This is not it. We served our notices, and once the 60 days runs, we're going to amend to add those claims back in.

And, your Honor, the purpose behind the statute, the Healthcare Liability Act, is to give the 60-day almost a cooling off period in which the defendants can look at what they're being accused of and can decide whether they want to settle the case or not, and it gives the parties an opportunity to work through it.

Well, not a single case has been settled in this litigation with any of the Tennessee entities.

THE COURT: Wingate was not Tennessee?

MR. STRANCH: That's not part of the Tennessee entities. That's Virginia.

THE COURT: Oh, yes.

MR. STRANCH: And the defendants can't in good conscience claim to the Court that they didn't know they were going to have claims against them because they were calling the plaintiffs, many of them, and letting them know that you may have gotten this and you may be sick. They were actively involved in an investigation with the Tennessee Department of Health where they were looking at people who had meningitis. So, any claim that they didn't know that someone was sick just should fall on deaf ears, your Honor.

Now, if you take a look at the *Stevens* case, which is from the Tennessee Supreme Court, the defendants have argued that it requires strict compliance with 121 and 122 for a claim to survive.

The Stevens case is different. It's from the

Tennessee Supreme Court. It's a very recent case and it says,

no, that's not correct. Substantial compliance is what is

required and that will meet the statute, and you have to also

show that there was a lack of substantial compliance and

prejudice to the defendants in order for a case to be

dismissed as a result of failing to meet the 121 and 122 pre
filing requirements.

And I would submit to the Court, even though the products liability actions are not included in there, for anyone that had a Healthcare Liability Act claim, the defendants can't show that there wasn't substantial compliance because they all got notices. They also can't show prejudice under any set of factors, your Honor.

In fact, if we need to brief that in individual -that needs to be looked at individual cases, because we've got
some cases where the medical records requests were sent and
they never even ordered them to look at them. They made no
effort to determine. So, there can be no showing of
prejudice.

So, where we stand, we have the stand-alone product liability actions, as we've said to the Court. Then there's the healthcare liability actions that were added later. And the defendants are suggesting that because of that statute of limitations conundrum, all those cases, those 40-odd cases, should be dismissed, with no right to recovery for the plaintiffs, and we believe that is inconsistent with the products liability statute, as you heard Mr. Nolan explain how that statute works. We believe it's inconsistent with the legislative purposes that the legislature has put forward for the products liability action, and we also believe that that would be inconsistent with the Stevens case that says to get a case dismissed for problems with 121 and 122, you have to show

two things, actual prejudice and there was a failure of substantial compliance, and those things cannot be met by the defendants and, in fact, your Honor, there's no affidavit, no declaration, no allegation by the defendants that they've been prejudiced by this at all. And so, those -- that must be denied.

The last aspect I want to talk about quickly again is the 122 claim. That is the certificate of good faith that you heard about earlier that says when you have an -- when you file one of these cases, you have to certify that they've conferred in good faith with an expert.

One of the things you need to know about that, your Honor, is -- actually delve down into the statute, the certificate of good faith only arises in cases in which part of your proof is that there is a violation of the standard of care. Products liability actions do not have a standard of care. It's a strict liability standard. I don't have to put someone on in a products liability case to say what the standard of medical care was in a community. That's not part of it. It's not something that's considered because you're talking about the product, was it defective. And so, if you look at it -- that's Section 29-26-115, it goes through and defines exactly what you have to do.

So, that evidence that you would have to have to do that would be the recognized standard of acceptable

are --

professional practice in the profession and the specialty thereof, if any, and that the defendant practices in the community in which the defendant practices or in a similar community at the time the alleged injury or wrongful action occurred.

The next portion of that is that the defendant acted with less than or failed to act with ordinary and reasonable care in accordance with that standard in the community.

None of this applies to a products liability action, your Honor. So, even if the Court were to say I think you may need to comply with Section 121 and give pre-suit notice for a products liability action --

THE COURT: Are you addressing those cases that you say you brought explicitly as product liability cases or all cases? Because there are some that are not just that, right?

MR. STRANCH: That's right. Well, your Honor, there

THE COURT: Are you talking about only the cases that were brought explicitly as product liability cases?

MR. STRANCH: These are the cases -- these are the 40-odd cases that were originally filed as only products liability actions and then after the notice period ran were amended to add in Healthcare Liability Act claims. They're pleadings in the alternative, is what they are.

THE COURT: But the argument that you're making now

doesn't apply to any other cases that were not brought in one way or another as product liability, right?

MR. STRANCH: Yes. So, any complaint that doesn't have a product liability action, this doesn't apply to.

THE COURT: Okay.

MR. STRANCH: But I believe all the complaints do have a product liability action. The question is whether they were filed after the notice ran or not, and we don't think that the 122 certificate of good faith applies to a product liability action because there's no requirement of showing what the standard of care is within a community as required under 115.

So, we think that the 122 should be denied out of hand, request on that, and as we've already explained, the defendants can't meet the requirements of 121 because they can't show any prejudice whatsoever, nor can they show that we didn't substantially comply, because every one of those cases now has notice that's been served. The notice has been filed with the complaint. The medical records releases were given to the defendants. They have everything now.

Their real argument is you filed a products liability case and then 60 or 90 days later, you amended to add it and, you know, you can't do that. It's a strict compliance argument, which the Tennessee Supreme Court explicitly rejected in the *Stevens* case. And so, we think that should be

1 denied and those cases should be allowed to go forward to 2 discovery, your Honor. 3 Do you have any additional questions for me that I can address? 4 5 THE COURT: No. 6 MR. STRANCH: On those issues? 7 THE COURT: I do not. 8 MR. STRANCH: Okay. Thank you. 9 THE COURT: Is there anybody else on the plaintiffs' 10 behalf? 11 MR. CLAYTON: Yes, your Honor. Daniel Clayton. I 12 should be five minutes, and it's on the issue -- and this is 13 an important issue because the Saint Thomas Clinic defendants 14 represented by Mr. Gideon and Mr. Tardio have moved to dismiss 15 virtually every case, Tennessee case, for an alleged failure 16 to comply with 121. 17 And if you would, please, turn to Tab 34. 18 going to guickly address how they are glossing over this 19 statute in much the same way that they are misinterpreting the 20 product liability statute, okay? 21 When a notice letter is sent out, we have to include 22 certain things in that notice letter. The things that are 23 included in the notice letter are found under Section 2 of Tab 24 34 where it says, "The notice shall include." 25 To put this in context, the Tennessee Saint Thomas

Clinic defendants have said you did not include in this notice letter NECC, Ameridose, Barry Cadden, et cetera, those NECC related defendants. So, therefore, since you sued them, your case should be dismissed, period. That's what they are alleging.

If you look at the statute, Judge, the statute says exactly what the notice shall include, and under Section D it says, "A list of the name and addresses of all providers being sent a notice." All providers, healthcare providers, being sent a notice. Okay.

So, in this situation, if you have multiple healthcare providers and you've given notice to one healthcare provider, you have to let all the ones that you gave notice to -- you have to include them on a list in here.

The problem with their argument is, number one, NECC, Ameridose, Barry Cadden, they weren't healthcare providers.

They were manufacturers. Even in their brief they refer to them as manufacturers, not healthcare providers.

Number two, NECC, Ameridose and those NECC-related defendants were never sent notice because we didn't have an obligation or a duty to send them notice. MDL Order No. 6 specifically addresses this, because under MDL Order No. 6, which is found on Tab 40, it says -- on the second page of that exhibit, it says there's a waiver. If there happens to be any kind of pre-suit notice anywhere, any state in the

country as to these NECC-related defendants, it's waived. You don't have to send them notice. It's waived.

And on top of that, underneath Paragraph E it says,

"Any pleading or motion asserting the applicability of any
state lawsuit requirements described herein, whether

considered procedural or jurisdictional, is deemed struck as
to these parties." All right.

So, the Tennessee Saint Thomas Clinic defendants are trying to rewrite -- if you go back to Tab 34 -- the healthcare liability action, because when the notice letter is sent out, we only have to include the names and addresses of all providers deemed sent a notice.

In terms of NECC, Ameridose, Barry Cadden were never sent notice so, therefore, they do not have to be on this list. There's no statutory requirement they be on the list, period.

Then the Saint Thomas defendants are saying you need to dismiss these cases because they didn't give us a HIPAA authorization allowing them to get the records from NECC, Barry Cadden and that crew, but if you look at Subsection E, under what the notice shall include, that's on Tab 34, it says the exact same thing here, a HIPAA-compliant medical authorization permitting the provider receiving the notice to obtain complete medical records from each other provider being sent a notice.

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NECC, Ameridose and those NECC defendants were never sent a notice. We had no obligation to include them on some list. We had no obligation to include them and no statutory requirement to give them a medical authorization form to get records that NECC wouldn't even have because it's -- the Tennessee clinic defendants sent them a list of names and they weren't patient-specific restrictions. They just sent them a list of names, including Mickey Mouse. So, maybe if I represent Mickey Mouse, maybe NECC would have records on that, but I doubt it, but it shows the absurdity of their position, Judge, and it's a good ending point because it covers so much of what's going on before us today. Thank you, Judge. THE COURT: Thank you. Any other plaintiffs wish to be heard? MR. STRANCH: Your Honor, unless you have specific questions for the plaintiffs, we'll rest on our papers. THE COURT: Thank you. Any defendants who wish to have brief reply or --MS. GREER: Yes, your Honor. THE COURT: Wait a minute. You have not spoken yet and -- I'm sorry. Your name. MR. BLUMBERG: My name is Jay Blumberg, but I'm with the Premier defendants. THE COURT: Right. You have not had a chance to talk? MR. BLUMBERG: Correct. Would you like the replies

first? How do you --

THE COURT: No. You go ahead.

MR. BLUMBERG: Okay. Your Honor, our motions to dismiss are obviously fully set out in our papers, but I want to just touch on a few of them.

The first and I think the one that may be the easiest to decide by the Court is whether my defendants are subject to the Product Liability Act, and I think caselaw and the statute, more specifically the statute in New Jersey, is clear that professionals who are engaged in the practice of medicine are not subject -- are not sellers under the Product Liability Act if, in fact, that product is being utilized as part of the medical care that's being rendered.

I don't think there's any question in this case -and if you look at the plaintiffs' reply brief, they basically
almost acknowledge that, in fact, these entities are not
subject to the Product Liability Act, and I would submit to
the Court that based upon that, all claims with respect to
product liability should be dismissed against all of the
Premier defendants.

In addition to the fact that they are not subject to the Product Liability Act, I would also submit, your Honor, that they're also not subject under the statute to the Consumer Fraud Act, because the Consumer Fraud Act is also very specific that when there are learned professionals

involved in the rendering of medical care, that, in fact, they are not subject to the Consumer Fraud Act and, in fact, there is at least one case, *Macedo vs. Dello Russo*, which indicates that -- it continues to identify that learned professionals are beyond the reach of the Consumer Fraud Act and even look to the legislature to change that if the legislature wanted to do so. That was back in 2004, I believe, and, in fact, no action has been taken by the legislature.

So, it's clear that the learned professionals, which would be my clients in this case, the Premier defendants, are beyond the reach of the Consumer Fraud Act.

The third thing that I would like the Court to take knowledge of is -- and I will say that some of my arguments are the same as Mr. Gideon's with respect to civil conspiracy and with respect to the agency claims as well, that there is no -- in terms of even the pleadings, there is no allegation -- or there is no credible allegation in this case that, in fact, there was a civil conspiracy. There was no allegation of an agreement.

And, in fact, in our case, as -- I don't think anybody can point to a situation in the New Jersey case where an individual who was identified on those order forms did not get the medication, and I would submit to the Court that those individuals did get that medication. So, I would submit that the civil conspiracy claim should be dismissed as well.

And then, finally, your Honor, I will -- the agency claim as it relates to the fact that my client should somehow be responsible for the conduct of NECC, it's just not borne out by any facts that have ever been pled. We purchased a product from NECC, and there is no credible evidence -- there's no credible pleading that, in fact, shows that we are somehow now responsible for the product that we purchased from NECC.

And, again, I know I said "finally," but the last thing is battery. The plaintiffs allege -- seriously allege that we committed battery because we didn't tell patients that we were going to inject a contaminated steroid into their back, and there was never anything that could ever be shown -- and I don't even think it's pled -- that we had any knowledge whatsoever that that was the case.

So, I would submit to the Court for those reasons, I would ask the Court to dismiss those cases -- or those claims at this juncture and it's appropriate to do it at this juncture because of the fact that -- the way the pleadings are structured.

THE COURT: Thank you.

(Discussion off the record.)

THE COURT: All right. Now, you want to talk to

Premier?

MR. COREN: Yes, your Honor. Michael Coren. Once

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      again, co-chair of the creditor's committee, and also I'm a
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      plaintiffs' counsel with matters that are pending -- one
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      matter that is pending against Premier and several others to
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      come.
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               I'm going to divide our argument. I just want to
      handle factual issues, factual issues and some legal issues my
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      colleague, Mr. Thomas Martin, is going to address with you,
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      your Honor.
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               THE COURT: How much time do you --
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               MR. COREN: Me, I'm only going to need about five
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      minutes, maybe six minutes, okay, because I've got -- I just
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      have --
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               THE COURT: I have one case after I finish with you.
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               MR. COREN: I understand, your Honor. Okay.
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               Your Honor, they say that there is no conspiracy, no
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      agreement going on here, and it's mind boggling that across
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      the country, clinic after clinic is submitting bogus
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      prescription order forms in the same way as Tennessee did.
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      It's the same way that --
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               THE COURT: What do you mean?
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               MR. COREN: What I mean by that, your Honor, is
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      they're taking all old fictitious names or they're taking
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      former patients and they're putting those former patients down
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      on the prescription order form and the order form is attached
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      to my -- my declaration.
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THE COURT: What does it have to do with this case?

MR. COREN: It has to do with the fact that they say there's no agreement, no conspiracy going on, and the point of fact of the matter is, clinic after clinic is submitting bogus lists to NECC and it has to be coming from both NECC and the clinic has to agree to do that. It is simply wrong to take an old name, put it on a prescription and send it in to get medication that's a controlled substance under Massachusetts law.

And, your Honor, Massachusetts law, when it comes to prescriptions from a compounding pharmacy, is controlling.

Why is that? Chapter 94 of the statutes of Massachusetts says so. At Section 19 they say that -- excuse me -- 17 they say out-of-state doctors' prescriptions will be honored, but they have to comply with Massachusetts law. Massachusetts law at 19 says no office supplies. You have to write a prescription for a respective plaintiff, a respective plaintiff fills it.

Then at 22, it says you have to have the doctor's name, the patient's name, which, by the way, it's also the law of New Jersey by regulation. A prescription has a patient name.

What were they doing? Patients would come in. They would administer steroid shots either in the back or in the hip or in the shoulder and then a couple of days later to renew their office supply, they put the order form and, once again, it's in our declaration -- my declaration that we

submitted to you in response.

And on Page 3 of my declaration, there's a chart, your Honor, and if you take a look at that chart, you're going to see that for patient -- because we filed under seal, I'm going to refer to patient one or two. Patient one, date of injection, 6/27/12. Date of purported prescription, the same day, 6/27/12. The purchase order date, that date. When does the drug actually get shipped? Two days later. Now, how do you go back in time in this particular matter? You can't. Other prescriptions are filled several days or several weeks later.

So, what was going on here is, once again, to get office supplies, in violation of Massachusetts law, which is by statute governing, they were falsifying or sending in bogus prescriptions. That violates Chapter 93A because they decided to come here to Massachusetts. So, Massachusetts Consumer Protection Law for that violation is going to be applicable.

Two, it actually also violates -- because now they're giving somebody else's prescription to my client, his client and other New Jersey clients -- patients, that violates the law. And the next thing is that they're charging them for Depo-Medrol, not a knock-off compound that they bought cheaper, but a prescription medicine. So, what it is in New Jersey -- and I know I'm going to segue for a moment into the law. I apologize, Bob.

But in New Jersey, where you're dealing with the economics, the business, the front end of -- the business end of the medical practice, that's covered under the New Jersey Consumer Fraud Law as well.

And I would propose to you, your Honor, that both statutes, both apply because they're not mutually exclusive.

Both states have an interest in protecting it. Both can apply and it's an issue of dual sovereignty, not choice of law, as to that.

So, your Honor, I ask that you seriously do take a look at my affidavit. I think you'll be able to follow it.

Once again, we summarized it into a chart for your convenience, but I think it all bears out, you know, with the documents that we've submitted. So, yes, there was an agreement. Yes, the CFA can apply.

As to the other legal issues, I would like to yield to my colleague.

THE COURT: Thank you. Mr. Martin.

MR. MARTIN: Yes, your Honor. I will be brief and try not to repeat the things covered in the briefs here, but I first want to clarify a point which may be a little ambiguous, and that is with respect to the application of the New Jersey Product Liability Act to this motion.

The master complaint that was filed here does not have any claim under the New Jersey Product Liability Act.

The New Jersey committee made a conscious decision not to make a claim under that act because of the specific provision that it has which is different than, as I understand, the Tennessee law, that delivering a product in the course of medical treatment is not selling the product for the purposes of product liability law. So, that act really doesn't have any application to this motion.

What the defendants did is they made a claim that negligence actions are barred because there is a product involved and that's how they brought in the Product Liability Act. That claim is not borne out by any of the decisions in New Jersey that have looked into that issue.

Specifically, there's a couple of cases that we've cited in the brief that involved blood supplies that were tainted with HIV, and the court specifically held that for policy reasons, they were not going to apply strict product liability law, but that if there is a fault proved against the medical provider in connection with the providing contaminated blood products, that negligence claim can proceed, and that's exactly what we have here.

There's also a decision that we cited, the *Estate of Halbert Finich* (phonetic), which was not addressed by the defendants in their reply memorandum that involved tainted blood with hepatitis and, again, the court said the same thing, that we're not going to apply the Product Liability Law

here, but we will allow for a claim of ordinary negligence, and that's what we have here.

So, I didn't hear Mr. Blumberg even address the issue of whether the negligence claims should proceed here. I think it's clear that the negligence claims presented in the master complaint do survive and should proceed.

With respect to the battery issue, again, I'll try to be very brief. The defendants' motion stated that under New Jersey law, there is no claim for battery in connection with failure to provide sufficient information in obtaining consent to a medical procedure, and that's not exactly true, because what New Jersey law does provide is that a claim of informed consent -- lack of informed consent does not lead to a battery. However, if you obtain consent for one type of procedure and perform another one, that is a battery. Specifically, that the caselaw in New Jersey addressed the issue of a patient who said they objected to the use of a cadaver bone in a bone-grafting procedure --

THE COURT: How does that apply in this case? I mean, are you suggesting that they only gave consent to good --

MR. MARTIN: No, your Honor, that's not it. It's not only they gave consent to non-contaminated products. They gave consent to the Depo-Medrol product, which is an FDA-approved product manufactured under FDA guidelines. They did

not give consent to the compounding situation which we have here and which as a result of the compounding errors, led to the harm.

So, it's similar to the case that we cited and it's also cited by the New Jersey Supreme Court, Ashcroft, where there was a transfusion and the patient said that, My family members gave blood and I was -- gave consent to be transfused with their blood and, yet, what the hospital did was give them a transfusion from general supplies of blood, and the California court found that that stated a cause of action for battery and, similarly, the Arizona court that we cite found that if you give consent for one type of anesthetic, that does not give the physician the right to administer a different type of anesthetic.

That's almost exactly on point with what we have here. Giving consent to one type of injection does not shield the medical professional from a claim of battery for administering a different product entirely.

Just very briefly with respect to the agency claims here, the master complaint alleged that the NECC entities were acting on behalf of the New Jersey medical providers when they compounded the materials and delivered to New Jersey. As they're an agent in doing that, the Premier defendants are responsible.

In response, the defendants in their motion state

that under New Jersey law, an agent, if it's an independent contractor, does not provide liability to the principal, but what we pointed out is that if the principal hires an incompetent agent, then that agent's actions do give liability to the principal.

The defendants don't contest that in their reply memorandum. What they said is that the master complaint does not allege sufficiently that the NECC entities were incompetent.

I think, frankly, your Honor, that's just silly.

There's hundreds of paragraphs of allegations detailing the incompetence of the NECC defendants. So, I think that, again, the agency principle should apply.

I think Mr. Coren adequately explained the factual nature behind our conspiracy claim and I won't prolong that.

With respect to the Consumer Fraud Act, New Jersey decisions are quite consistent and proudly assert that the New Jersey Consumer Fraud Act is perhaps the broadest and most consumer friendly Consumer Fraud Act in the country. The claim that a medical professional cannot be sued under Consumer Fraud Act because they are learned professionals is just wrong. You can't sue them under the fraud act for actions taken as part of their profession.

However, here what we've alleged is that these medical professionals acted as merchants and with a common

plan, which the NECC defendants figured out a way to get a product outside of the FDA scope of scrutiny and have it cheaper and increase everybody's profits. They were acting as a merchant when they did it, and we should be allowed to pursue the discovery on that claim as well, your Honor.

THE COURT: Thank you. If I absolutely must hear any replies, you got three minutes total.

MS. GREER: Your Honor, I'll make it very brief, but I do think it's a little unfair that we were given five pages to do a reply and had to get everything in and now they come forward with a book of evidence that they haven't cited in pleadings and we haven't had a chance to respond to. If the Court would prefer to do supplemental brief, we could come back and explain these things.

The evidence does not add up any more than the bus allegation. We explained in our reply that the bus and the "one healing community, the one name," doesn't even include STOPNC. So, how that could be evidence of alter ego is beyond me. It's clear from the Website that that's not even part of it.

I'll leave it to you as to how you would like me to go through each of these pieces, but they do not support the allegations that they are making now and they don't overcome the strong presumption.

THE COURT: Mr. Gideon.

MR. GIDEON: Yes, your Honor.

I'm not going to characterize the arguments you heard as absurd, but I do want to respond to a little bit of the hyperbole.

Mr. Nolan told you that if you decided in our favor, you would be changing law of Tennessee, and that's absolutely inaccurate. Our position is supported by the published case of Burris vs. Hospital Corporation of America, decided in 1999, that dealt with a case much like this where there was care provided and allegedly a defective product, and the holding was the Malpractice Claims Act provided the sole substantive basis for evaluating the defendant's liability.

The carve-out that they referred to, 29-28-103. The one point we agree on is Senator Thelma Harper sponsored the 25-year statute of repose, but we cited the legislative history in which she was asked, What's this deal with? And she said, This does not deal with malpractice. This deals only with a product.

Article II, Section 17 of the Tennessee Constitution, if it applied in Washington, we wouldn't have the problems we have with legislation because it says any bill can only address one subject and that subject has to be in the caption. And you know what the caption of that act was that Mr. Nolan relied on to completely changed the law? The caption was, "An act relative to statute of limitations." It clearly was not

1 intended to carry out the result he intends to get you to accept. 2 The Healthcare Liability Act clearly applies. 3 Paragraph 17 of the master complaint makes it clear they're suing us for providing services. 4 5 Two additional points. The binder that Ms. Greer 6 referred to a moment ago, don't you think if there was a 7 single document that supported the argument that there was a 8 sale of MPA, it would be somewhere in that binder that was 9 just given to us right before the argument? And it's not 10 there, not at all. 11 Finally, Tennessee law does not have any transaction 12 -- doesn't treat any transaction as one where it's part 13 product, part service. You look at the predominant feature 14 and if the predominant feature is service, the Healthcare 15 Liability Act applies. Thank you. THE COURT: Thank you very much. I will take the 16 17 papers of all of you. I thank you for the good briefs. I 18 thank you for your indulgence in this rather both truncated 19 and confused hearing. I apologize for that. 20 MR. GIDEON: Thank you. 21 MR. STRANCH: Thank you, your Honor. 22 (Adjourned, 4:42 p.m.) 23 24 25

## CERTIFICATE

I, Catherine A. Handel, Official Court Reporter of the United States District Court, do hereby certify that the foregoing transcript, from Page 1 to Page 69, constitutes to the best of my skill and ability a true and accurate transcription of my stenotype notes taken in the matter of No. 13-md-2419-RWZ, In Re: New England Compounding Pharmacy, Inc., Products Liability Litigation.

June 29, 2014	/s/Catherine	А. Н	landel_	
Date	Catherine A.	Hand	el RPR-CM,	CRR